

# Improving treatment options and outcomes with Vivitrol

The 23 million individuals in America with substance use disorders (SUD) often represent the most resource-intensive population in our health care systems, amounting to billions of dollars in lost human, economic, legal, and social costs. While morality and individual choice were once thought to be primary culprits of addiction, evidence now shows that the inability to abstain, limited behavioral control, dysfunctional emotional and interpersonal responses, and other addiction behavior are due to long-term changes in brain circuitry. Addiction is thus a long-term, chronic condition resulting from a complex interaction of biological/genetic vulnerability, psychological influences on thinking and behavior, and environmental variables. Accordingly, the National Quality Forum (NQF), the World Health Organization (WHO), and best practices recommend a tailored combination of psychosocial treatment and appropriate medication to treat SUDs.

Medication-assisted treatments (MAT) are evidence-based interventions that have been shown to increase patient retention in treatment, social functioning, and days of abstinence, while reducing engagement in criminal activities, infectious disease transmissions, and hospital and emergency room admissions. However, few U.S. Food and Drug Administration (FDA)-approved medications are currently available for SUD treatment. Buprenorphine, methadone, and naltrexone (oral and injectable) are the most commonly used MAT for alcohol and opioid use disorders.

Methadone and buprenorphine are opioid medications that provide substitution therapy. While reducing some pain and drug use behavior, these medications may also produce euphoria, cause dependency, and can be diverted to the underground market. On the other hand, naltrexone reduces

the biological response to opioid use by occupying the opioid receptor in the body without activating it, and thus does not induce euphoria and is not habit-forming. However, oral naltrexone must be taken every day, and without the enforcing effect of pain-relief or euphoria, poor compliance with the oral formulation of naltrexone has limited its usefulness.

As a result, the FDA approved an extended-release, injectable form of naltrexone, Vivitrol, in 2006 for treatment of alcohol use disorders, and in 2010 for opioid use disorders. While it has the same effects as oral naltrexone, it requires only a monthly injection. For many, removing the daily challenge of choosing between taking naltrexone or getting high could buy them the time, in monthly increments, to progress in their treatment and develop the strategies necessary for recovery.

As with any medication, there are side effects to Vivitrol, the most common of which include fatigue, nausea, headache, and injection-site reactions, which can be reduced by proper training.<sup>1</sup> It can cause immediate withdrawal symptoms if taken in conjunction with narcotics, and should not be prescribed until the patient has been through opioid withdrawal. It is also notably more expensive than other MAT. However, several studies have shown that the higher costs can be offset by higher rates of treatment adherence and medication persistence, lower inpatient utilization, and overall reduced use of costly healthcare services.<sup>2,3,4,5</sup>

Vivitrol is not the only or best medication for everyone. Patients, physicians, and providers should be well informed about the drawbacks and benefits of including it as part of a treatment plan, and take into consideration the particular biological, psychological, and social environment that affect each individual's treatment. However, studies and accounts show that for many, in conjunction with psychosocial treatment, Vivitrol best improved treatment outcomes, enhanced quality of life, and reduced health spending.

Unfortunately, access to Vivitrol remains a challenge. Vivitrol is not available to general Medi-Cal patients without

<sup>1</sup> Cousins, S.J., Denering, L., Crevecoeur-MacPhail, D., Viernies, J., Sugita, W., Barner, J., Kim, T., Martinez, J., Weimann, S., & Rawson, R., (in press). A demonstration project implementing extended-release naltrexone in Los Angeles County.

<sup>2</sup> Baser, O., Chalk, M., Rawson, R., & Gastfriend, D. R. (2011). Alcohol dependence treatments: comprehensive healthcare costs, utilization outcomes, and pharmacotherapy persistence. *The American Journal of Managed Care*.

<sup>3</sup> Hartung, D. M., McCarty, D., Fu, R., Wiest, K., Chalk, M., & Gastfield, D. R. (2014). Extended-release naltrexone for alcohol and opioid dependence: a meta-analysis of healthcare utilization studies. *Journal of Substance Abuse Treatment*, 47(2), 113-121.

<sup>4</sup> Id.

<sup>5</sup> Kennedy, J., Dipzinski, A., Roll, J., Coyne, J., & Blodgett, E. (2011). Medicare prescription drug plan coverage of pharmacotherapies for opioid and alcohol dependence in WA. *Drug and alcohol dependence*, 114(2), 201-206.



an approved Treatment Authorization Request (TAR), a lengthy pre-authorization process. Additionally, lack of insurance coverage and sufficient knowledge of Vivitrol deters many providers from recommending it. Studies show that when Vivitrol is covered under the Medicaid program, and awareness and misconceptions are addressed, utilization greatly increases by 100% or more.<sup>6,7,8</sup> Thus it is important to properly educate providers and patients about Vivitrol, and work with insurance providers and Department of Health Care Services to ensure that Vivitrol is readily accessible on the Drug Medi-Cal formulary.

Individuals with SUDs and other chronic illnesses need access to medications that are optimal for their health, and physicians and providers need the full range of treatment options with which to treat their patients. It is crucial to implement funding policies and medical infrastructure to reduce the costs of Vivitrol and other important medication for effective SUD treatment. For many, Vivitrol can make the crucial difference between recovery and relapse, and it, as well as other medication-assisted treatment, needs to be a viable, accessible, and informed option on the pathway to recovery.

### **Policy and Program Recommendations**

**Work with state partners at the Department of Health Care Services to ensure that all MAT approved by the FDA, including Vivitrol, is available on the Drug Medi-Cal (DMC) formulary without the need for a Treatment Authorization Request (TAR).** Including Vivitrol on the DMC formulary without the need for a TAR would reduce barriers to accessing this potentially lifesaving medication. Currently, Vivitrol and acamprosate are the only two addiction medications not included on the DMC formulary.

**Work with local, state, and federal partners to increase funding and resources for infrastructure and workforce development for the SUD system that support the expanded use of Vivitrol and other MAT.** In California, only 2-3% of the SUD workforce is medically trained. The shortage of prescribers with addiction expertise and the challenges of financially supporting and competing for these limited specialists are significant barriers to the greater use of FDA-approved addiction medications. Competitive DMC reimbursement rates, specialized trainings, and technology infrastructure, such as telehealth, could expand the number and reach of addiction providers.

**Explore opportunities to leverage 340B pricing to take advantage of federal resources and maximize value through discounted pricing on these addiction medications.** The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations at reduced prices. Inclusion of these addiction medications would allow greater access to eligible patients and provide more comprehensive services.

**Collaborate with county departments and community partners (e.g., health plans, community clinics, etc.) to increase the understanding of the use of medications for addiction, such as Vivitrol.** While any licensed physician can prescribe Vivitrol, most physicians only feel comfortable prescribing this medication with the appropriate training and experience. As such, provider education and mentoring will be essential to expanding the number of MAT prescribers.

**Work with SUD programs to identify and reduce barriers to accessing Vivitrol and other MAT.** Whether access challenges are related to a lack of prescribers, misconceptions about the use of medications to support recovery, funding challenges, or other reasons, efforts should be taken to identify and reduce such barriers to access.

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<sup>6</sup> Leslie, D.L., Milchark, W., Gastfriend, D.R., Herschman, P.L., Bixler, E.O., Velott, D.L., Meyer, R.E. (2015) Effects of injectable extended release naltrexone for opioid dependence on residential rehabilitation outcomes and early follow up. *Am J Addict.*

<sup>7</sup> Crevecœur-MacPhail, D., Ransom, L., Cousins, S., Vazquez, E., & Rawson, R. (2012). Impact of Vivitrol Use in Los Angeles County Treatment programs. Presented at the Addiction Health Services Research conference in New York.

<sup>8</sup> Crevecœur-MacPhail. (2013). Establishment of Performance measures for Substance Use Disorder Treatment in Los Angeles County, California. Presented at the Annual Meeting of the College on Drug Dependence in San Diego, CA.